

Preamble

Since the specific device used in a surgical procedure is the means with which that surgical procedure is carried out, it is consequently necessary to explain the basic differences between the different devices.

The prior art to present application teaches about realization of a stapled circular anastomosis by the aid of either a rigid annular stapler or a flexible annular stapler. These two kinds of annular staplers constitute the two categories/families of circular staplers actually known in the art.

It is evident that surgical procedures or methods involving the use of a circular stapler for anastomosis depend on the technological characteristics the stapler offers. Moreover, those methods or procedures are dictated by the context of open surgery (in which the abdomen or chest are opened) or closed surgery (in which those spaces are not opened). The technological characteristics of a stapler must consequently be also adapted to the context of open or closed surgery.

The rigid annular stapler is the older one and corresponds to the basic prior art for realizing a circular stapled end to end anastomosis. US Patent No 5,314,435 to Green et al. – cited by the Examiner- uses that category/family of rigid annular staplers. The flexible variety to Bessler et al. described in US 5,411,508 – also cited by the Examiner- is a progress as to the rigid version. It came to solve some major disadvantages of the rigid version. Indeed, the rigid version –because of the rigidity of its structure- precludes its use for other than straight intestines "*such as only about 15% of colon anastomoses are within reach with it through the rectum*" (This quotation is from Bessler's 5,411,508 and it refers to the rigid annular stapler like the one used by Green in 5,314,435).

Office Action Summary

The Examiner has rejected claims 32 and 35-40 under 35 U.S.C. 112, as being indefinite.

The Examiner has rejected claims 23,24 and 27 under 35 U.S.C. 102(b) as being anticipated by Green, et al. – 5314435 (D1)

The Examiner has rejected claims 23, 24 and 27-34 also under 35 U.S.C. 102 (b) as being anticipated by Bessler, et al.-5411508 (D2).

In view of the following remarks, the Examiner's rejections under 35 U.S.C. 102(b) as to D1 and as to D2 are respectfully traversed.

Claim Rejections – 35 USC §112

The Examiner has rejected claims 32 and 35-40 as being indefinite and not complying with 35 U.S.C. 112, second paragraph. These claims have been rewritten so as to comply with 35 U.S.C. 112 and are consequently deemed to be in order.

§102(b) Rejections – Green US 5 314 435 (D1)

Independent claim 23 and its depending claims 24 and 27 are under this item.

Claim 23 discloses a surgical method for realizing any variety of circular anastomosis (i.e. end to end, end to side, side to end or side to side) in any chosen area between two hollow organs or segments predefined by a surgeon. This by the means of a flexible annular stapler having two round invertible jaws that can answer various surgical situations met by the surgeon as described in present specification page 13, line 19 – page 14, line 11. The surgical procedure under consideration is realized under conditions of closed surgery (i.e. without any invasive opening of the abdomen

or chest spaces) and doesn't require neither disconnection/removal of any of the jaws nor means for that disconnection during the dealt procedure.

It is also to be noted that claim 23 describes a surgical method applicable in all types of anastomoses (end to end, end to side, side to end and side to side) and capable of fulfilling the requirements of different surgical procedures whether the lumen of the diseased hollow organ is obstructed or not.

Figures 11, 12 and 14 in the present specification are three illustrations of the surgical procedures described in claim 23. Written support for these illustrations of claim 23, can be found in the specification in page 24, line 17 – page 26, line 10 and in page 27, line 8 – page 28, line 2. Those procedures are realizable either under open or closed surgery (as clearly stated in page 24, lines 3-5 in present specification) even though that claim has been limited to closed surgery only, in order to expedite the prosecution.

Contrary to the Examiner's statement, what is **precisely** disclosed in D1 is a method of performing an end to end anastomosis in colo-rectal non tumor-obstructing lesions, realized under (abdominal) closed surgery conditions and including the following steps:

- * Introducing an anvil delivery system (as a distinct separate means) through the anus (natural opening) into a colon's lumen through the rectum beyond a diseased colon portion to be excised (and thus implicating a clear lumen indecmn of any obstructing lesion such as a tumor !!!);
- * Detaching the anvil jaw from the delivery system, which in itself is removed thereafter out of the anus;
- * Excising the diseased colon portion;
- * Closing the ends (eventually) by means of a linear stapler;
- * Introducing through the anus a rigid annular stapler naked from its anvil;
- * Maneuvering so as to retrieve a hidden rod of the anvil;
- * Connecting the anvil rod with a stapling jaw mounted on a short rigid shaft for realizing an end to end anastomosis at a (an obligatory) short distance from the anus.

Clearly, there are lots of differences between the method described in claims 23 (and further 24 and 27) to present applicant and the method described in D1 to Green.

The following comparative table summarizes some of the differences:

Surgical method description	Toledano (claim23)	Green
Surgical conditions of work	Open and Closed surgery of the thorax and/or the abdomen	Closed surgery of the abdomen only
Surgical device(s) used	Flexible annular stapler	Rigid annular stapler (commercially entitled EEA) + anvil delivery system
Type of anastomosis described	All kinds of anastomoses (end to end, end to side, side to end and side to side)	End to end
Anastomosis location	Any predefined chosen area between two parts of same or disparate hollow organs (between gallbladder and duodenum for example)	Obligatorily limited to few centimeters from the anus
Type of hollow organ suitable for application of the method	Any hollow organ	Limited to left (sigmoid) colon
Natural openings usable for application of the method	Mouth (alimentary tract and respiratory airways) and Anus	Anus only
Artificial openings described in the method	Yes	No
Necessity of a clear lumen in the diseased portion to be excised for applying the surgical method	No	Yes
Particular technological feature of the device described in the claim : invertible jaws adapted to the surgical needs of the surgical procedure	Yes	No
Necessity of any removable anvil for applying the surgical method described in	No	Yes (obligatory)
Necessity of an anvil delivery system	No	Yes

Obviously, if the surgical methods in front of us were the same, the answers in the columns Toledano and Green in the table above would have also been the same. Applicant is hence strongly convinced that independent claim 23 and its depending claims 24 and 27, are novel and inventive and have not been anticipated by Green (D1).

§102 (b) Rejections –Bessler US 5 411 508(D2)

The Examiner has rejected the previously discussed independent claim 23 and its depending claims 24 and 27 as being anticipated also by Bessler in D2.

Examiner's rejection as to these claims is respectfully traversed.

First, Bessler's disclosure (D2) does not deal with surgical methods at all. Bessler discloses a flexible annular stapler for use in open surgery conditions with the object of overcoming the limitations of the rigid annular stapler version such as the one dealt with above in D1. (See chapter " Background of the invention " in D2).

Column 14 lines 3-46 and fig. 4 of D2 - mentionned by the Examiner as a support to Bessler's anticipation -, do not disclose a novel nor inventive surgical method. Bessler gives here an example of how his stapler could be used through the anus in a medical case identical to that described by Green (in D1) -namely, a resection of a diseased sigmoid colon portion in a situation of non obstruction of the colon's lumen by a tumor lesion. The resection of the diseased portion is realized in D2 by traditional open surgery using invasive surgical tools as stated by Bessler himself (see D2; col.14, lines 13-16). As in D1, an end to end joint is realized. Fig. 4 in D2 to Bessler illustrates two ends of tubular colon to be joined by end to end anastomosis as clearly also stated in col.14 lines 3-6 of D2. Further, col. 14, lines 7-46 in D2, describes the realization of that anastomosis by insertion of the flexible annular stapler to Bessler through the anus.

It's clear that even if the indefinite example given by Bessler in D2 is to be considered as a prior art surgical method, claims 23, 24 and 27 to present applicant, remain nevertheless novel and inventive. Neither the conditions in which the method is realized [open -invasive- surgery in D2 versus closed -non invasive- surgery in present application] nor the steps of the described method and its applications (to any hollow organ/segment) are same or comparable. Furthermore, neither the results obtained (in term of variety of anastomoses realized), nor the technological characteristics of the stapler (presence or not of invertible jaws depending on the needs of the surgery) are same or comparable.

The Examiner has also rejected independent claim 28 and its depending claims 29-34 as being anticipated by D2.

The Examiner's rejection as to these claims is also respectfully traversed.

First, the arguments given above as to applicant's claims 23, 24 and 27 are relevant here too. Neither the conditions in which the method of claim 28 is realized [open invasive surgery in D2 versus closed non invasive surgery in present application] nor the steps which need to be adapted to the specific conditions of that closed surgery are comparable.

Moreover, independent claim 28 illustrated in Fig. 13 (and described in page 26, line 11- page 27, line 7) in present application deals with a method realized under

closed surgical conditions [-i.e. without any invasive opening of the abdomen or chest spaces-] in which:

- i) a flexible annular stapler having at least one detachable jaw is indispensable for realization of the procedure. This technological characteristic doesn't exist at all in the flexible stapler to Bessler precluding its use in same procedure.
- ii) The method necessitates inscription of a detachable jaw through the patient's body wall (i.e. through the abdomen or chest wall) and its attachment in the inside of a closed space (i.e. in the inside of a closed abdomen or closed thorax). Here again, we are out of the scope of D2 device and of D2 surgical conditions (i.e. closed versus open surgery).

In other words, not only the method of claim 28 has never been disclosed or even fairly suggested in D2 to Bessler, but also the technological characteristics of the device disclosed in D2 cannot allow to realize it (the dealt method).

In conclusion, not only have the surgical methods described in independent claims 23 and 28 not been anticipated by Green nor by Bessler, but they also cannot be applied neither with the rigid stapler to Green nor with the flexible stapler to Bessler.

Finally, in order to expedite the prosecution, the applicant has chosen to amend the independent claims so as to sharpen and emphasize the crucial differences between the method described by the applicant and those described by Green or by Bessler. Specifically:

- independent claim 23 (and its depending claims 24, 27) have been replaced by new independent claim 001 (and depending on claims 002 and 003);
- independent claim 28 (and its depending claims 29, 31-34) have been replaced by new independent claim 004 (and depending on claims 005 to 009);
- independent claim 35 (and its depending claims 36-40) have been replaced by new independent claim 010 (and depending on claims 011 to 015).

Now independent claims 001 and 004 recapitulate all the distinctions already discussed above between claim 23 and 28 as to the prior art to Green and Bessler. They explicit further, part of those distinctions such as to emphasize in an intelligible manner, the crucial differences with the prior art. Those precisions are underlined in the text of the new claims.

In view of the above amendments and remarks it is respectfully submitted that independent claims 001, 004 and 010, and hence their respective dependent claims 002-003, 005-009, 011-015 are in condition for allowance. Prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted


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Date: 20 May 2006